REMARKS

Claims 1 – 7, 10 – 22, 25 – 59 and 62 – 65 are pending. Claims 1 – 7, 10 – 18 and 23 – 24 have been cancelled.

1. Restriction requirement

Applicant acknowledges that the restriction requirement has been made final.

2. Double Patenting Rejection

Claims 19 – 22, 25 – 59 and 62 – 68 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 1 – 11 of copending patent application No. 10/277,264. Applicant respectfully requests that the rejection be reconsidered at the time either the claims of this patent application or the claims of copending patent application No. 10/277,264 are allowed.

3. Rejection of claims 19 – 22, 25 – 59 and 62 – 65 rejected under 35 USC 112(1)

Claims 19 - 22, 25 – 59 and 62 – 65 stand rejected under 35 USC 112(1). The PTO states in paragraph 5 of the Office Action that the specification only shows treatment of EAE by the claimed method by use of an Ig-peptide derived from one antigen, proteolipid, and that "the disclosure of one species on a genus claim so large does not adequately describe the invention." Applicant respectfully disagrees with the rejection.

Rejection of the claims under 35 USC 112(1) for lack of written description should be rare and there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. MPEP 2163 II.A; In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). The inquiry into whether the written description is met is a question of fact, that must be determined on a case by case basis and depends on the nature of the knowledge imparted to those skilled in the art by the disclosure. MPEP 2163 II.A; In re Wertheim, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976).

Claims 19 – 22, 25 – 33 are directed to a method of alleviating symptoms of an autoimmune disorder in an individual by administering to the individual an immunoglobulin or portion thereof

linked to an antigen wherein the immunoglobulin is capable of crosslinking Fc receptors present on the cell surfaces of an antigen presenting cell. Claims 34-59 and 62-65 are directed to either identifying a patient in need of enhanced levels of IL-10 or decreased levels of INFγ and then administering to the individual an immunoglobulin or portion thereof linked to an antigen wherein the immunoglobulin is capable of crosslinking Fc receptors present on the cell surfaces of an antigen presenting cell. In either set of claims, the composition must include an "immunoglobulin" or "portion thereof" capable of binding to an Fc receptor (which requires a conserved Fc portion of an immunoglobulin) of an antigen presenting cell. Thus, most of the composition is of a known structure. In addition, the immunoglobulin must be linked to an antigen, two of which are disclosed (PLP and MBP) and many of which are known to one of ordinary skill in the art. While applicant does not at all agree with the rejection, to expedite examination and to clarify the claimed invention, applicant has limited the number of autoimmune disorders mentioned in the claims 19-22 and 25 - 33 to multiple sclerosis, rheumatoid arthritis and insulin dependent diabetes.

Whether the specification shows that an applicant was in possession of the claimed invention is not a single or simple determination but is a factual determination reached by considering multiple factors. Factors include the level of ordinary skill in the art, partial structure, physical or chemical properties, functional characteristics alone or a disclosed correlation between structure and function, and the method of making the claimed invention. University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (CAFC 1997). Applicant has disclosed two such antigens, other antigens would be known to one of ordinary skill in the art, the specification teaches how to make the claimed invention and functional characteristics are well defined. Applicant has also narrowed the number of autoimmune disorders to a limited number in claims 19-22 and 25-33. Thus applicant believes that claims 19-22 and 25-33 are in fact allowable under 35 USC 112(1) and respectfully requests withdrawal of the rejection.

In claims 34 – 59 and 62 – 68, applicant's claims are directed to methods of reducing disease symptoms in an individual in need of either elevated IL-10 or decreased IFN-γ after the patient is identified to be a patient in need of such treatment. The claims are not specifically directed to inflammatory diseases as stated by the PTO. Applicant's construct is clearly shown to increase IL-10 and decrease IFN-γ levels as required by the claims. It is therefore unclear, based

upon the wording of the claims, why the claims are in violation of 35 USC 112(1) because the claimed construct achieves what is required (increase IL-10 and decrease IFN-γ levels) in a patient in need thereof regardless of the disorder the patient is suffering. Applicant therefore believes that there is ample written support in the specification for claims 34 – 59 and 62 – 68 and respectfully requests withdrawal of the rejection.

4. Rejection of claims 19-21, 28 – 37, 43 – 52 and 58 – 68 under 35 USC 102(b) over WO 90/09804

Claims 19 – 21, 28 – 37, 43 – 52 and 58 – 65 stand rejected under 35 USC 102(b) over WO 90/09804 ("Zanetti"). Zanetti teaches methods of making an engineered immunoglobulin. Virtually all of Zanetti is devoted to methods of enhancing an immune response or vaccination using the construct taught in Zanetti. On page 5, lines 31 – 35 through page lines 1 – 3 and the Abstract, Zanetti mentions that:

> The present invention is further directed to methods useful for building tolerance to certain antigens, including those associated with autoimmune diseases, or for down-regulating hypersensitivity to allergens, or for providing passive immunity against certain pathogenic antigens, by administering to an individual in perceived need of such, a novel immunoglobulin as defined above.

Other than the above language and that which exists in the Abstract, there are no examples or data in the Zanetti patent which shows the use of the Zanetti construct for treatment of autoimmune disorders and it is unclear how the Zanetti construct would be used for such a treatment. There is no teaching in Zanetti that the construct of Zanetti crosslinks Fc receptors on the surfaces of antigen presenting cells, a requirement of claim 19, 34, 49, 64 and 65. In order to properly anticipate a claim, every element of the claim must be found in a single prior art reference. MPEP 2131. Because Zanetti does not teach a construct capable of crosslinking Fc receptors on the surfaces of antigen presenting cells, it cannot anticipate claims 19 – 21, 28 – 37, 43 – 52 and 58 – 65 under 35 USC 102(b). Applicant respectfully requests withdrawal of the rejection. Nor would Zanetti obviate the claimed invention under 35 USC 103(a) in that there is no teaching or suggestion of a construct in Zanetti which crosslinks Fc receptors on the surface of antigen presenting cell.

Applicant hereby respectfully requests a three month extension of time. If there are any

questions concerning this response, applicant's attorney can be reached at the number stated below.

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